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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,465	04/01/2004	Sonia Moreno-Lopez	NHL-NP-45	8524

7590 09/22/2006

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EXAMINER	
WEHBE, ANNE MARIE SABRINA	
ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/816,465	MORENO-LOPEZ ET AL.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-20 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's preliminary amendment filed on 7/19/04 has been entered. Claims 1-20 are pending in the instant application. An action on the merits follows.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on applications filed in Germany on October 2, 2001 or November 12, 2001. It is noted, however, that applicant has not filed a certified copy of the DE 101 48 697.9 or DE 101 56 678.6 applications as required by 35 U.S.C. 119(b) or provided a translation of these documents in English.

Specification

The abstract of the disclosure is objected to because it uses legal phraseology, i.e. "means", and includes a recitation of 37 CFR 1.72(b). Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, see page 28. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The disclosure is also objected to because of the following informalities: the last line of page 29 recites "Serial No. _____".

Appropriate correction is required to fill in the blank.

Nucleic acid and/or Amino acid Sequences

This application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Pages 7-8, 22, and 23 of the specification, and claims 5-6, 15, and 16, all contain nucleic acid and/or amino acid sequences which are not identified by SEQ ID NOS. Please note that compliance to 37 CFR 1.821-1.825 requires that the specification and claims be amended to recite SEQ ID NOS. for each recitation of a sequence in the specification. Further, it is unclear whether these sequences are present in the paper copy and CRF of the sequence listing filed in this application. If the sequences are present in the paper and CRF listings, applicant may fully comply with 37

CFR 1.821 by amending the specification and claims to include the proper SEQ ID NOS. If the sequences are not present on the filed paper and CRF listings, then new paper and CRF sequence listings are required as set forth in the attached Notice to Comply.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 7/19/04 is in compliance with the provisions of 37 CFR 1.97 and has been considered by the examiner.

Please note that the listing of various U.S. patent, foreign patent, and non-patent references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892 or appear in the IDS submitted on 7/19/04, they have not been considered.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 7-11, and 17-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 10/816,591, hereafter referred to as the '591 application. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Claims 1-18 of copending application 10/816,591 represent a species of the instant invention as claimed. The instant claims are broadly drawn to the use of a DNA expression construct to elicit a Th1 type immune response and vaccine employing the DNA expression constructs. The '591 claims are more narrow and drawn specifically to the use of DNA expression constructs and vaccines comprising the constructs for immunization against leishmania. As such, the '591 claims represent a species of the instant broader claims. It is well established that a species of a claimed invention renders the genus obvious. *In re Schaumann* , 572 F.2d 312, 197 USPQ 5 (CCPA 1978). Therefore, the '591 claims render the instant claims obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, and 10-16 provides for the use of a DNA expression construct, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-6 and 10-16 are also rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 1-20 are further rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As noted above, claims 1-6 and 10-16 are directed to a "use" of a DNA expression construct without reciting any method steps. Claims 7-9 and 17-20 depend on claims 1 or 10 respectively. Claim 7 recites a "Vaccine ... employing the DNA expression construct according to claim 1" and claim 17 recites a "Vaccine ..employing the DNA expression construct according to claim 10. However, claims 1 and 10 are "Use" claims. Thus, it is unclear whether the applicant intends to claim a product, which is a DNA expression construct, in claims 1 and 10, or a method of using a DNA expression construct. Further, if the applicant intends to claim a method in claims 1 and 10, then claims 7-9 and 17-20 would be improper in that they are claiming a product based on a method claim. In addition, the use of the term "employing" in claims 7-9 and 17-20 is indefinite in that it is unclear whether the expression construct is part of the vaccine or whether the vaccine is separate from the expression construct and somehow uses the construct to elicit the intended immune response. As such, the metes and bounds of claims 1-20 cannot be determined.

In addition, claim 1 lack antecedent basis for "the coding sequence" and "the animal to be vaccinated"; and claim 11 lacks antecedent basis for "the immunizing polynucleotide sequences", "the coding sequence", and "the animal that is to be vaccinated". For the phrases "the coding sequence" and "the animal..", it would be remedial to amend the claims to recite "a coding sequence" and "an animal...". Claims 2-9, and 12-16, depend on claims 1 or 11 and thus are included in this rejection.

Claims 9 and 19-20 are also indefinite in that the phrase "for the application in human beings" is ungrammatical and appears to lack antecedent basis. It would be remedial to amend the claims to recite "for use in human beings" or "for administration to human beings".

Although claims 1-20 are indefinite as discussed in detail above, in the interests of compact prosecution, claims 1-20 have been searched and examined in so far as they recite a DNA expression construct or a vaccine comprising a DNA expression construct.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 7-15, and 17-20 rejected under 35 U.S.C. 102(a) as being anticipated by Schirmbeck et al. (June 2001) J. Mol. Med., Vol. 79, 343-350. The applicant claims a "use" of a DNA expression construct for intradermal injection to elicit a type 1 cellular mediated immune response where the DNA expression construct is a covalently closed linear DNA molecule comprising a linear double stranded region comprising a coding sequence under control of a promoter, where the single strands forming the double strand are linked a short single stranded loops of DNA, and where the construct is covalently linked to an oligopeptide. The applicant

further claims a vaccine employing said construct. In addition, the claims recite wherein the construct encodes HBsAg, and wherein the oligopeptide comprises PKKKRKV.

Schirmbeck et al. teaches a minimal expression construct (MIDGE) comprising covalently closed linear DNA that contains only an HBsAG coding sequence operably linked to CMV promoter and polyA termination sequence where the linear ends are linked by short single stranded loops of DNA, and wherein the construct is further covalently linked to the NLS oligopeptide PKKKRKVEDPYC (Schirmbeck et al., page 345, Figure 1 B.3). Schirmbeck et al. also teaches a vaccine comprising this construct (Schirmbeck et al., page 343).

Regarding the intended use as recited in the instant claims for intradermal injection to elicit a type 1 cellular mediated immune response, the applicant is reminded that the use of a product for a particular purpose is not afforded patentable weight in a product claim where the body of the claim does not depend on the preamble for completeness but, instead, the structural limitations are able to stand alone. The MPEP states that,".. in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art." *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto* , 136 USPQ 458, 459 (CCPA 1963)(MPEP 2111.02). Further, the intended use of the compound does not constitute a step in the method as claimed. As noted previously in this office action, the "Use" claims do not comprise any actual method steps. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure or composition, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. *In re Hirao* , 535 F.2d 67, 190

USPQ 15 (CCPA 1976); *Kropa v. Robie* , 88 USPQ 478, 481 (CCPA 1951). As such, by teaching the exact structural elements of the claims as written, Schirmbeck et al. anticipates the instant claims.

Claims 1, 7-11, and 17-20 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,451,593 (2002), hereafter referred to as Wittig et al. The applicant claims a "use" of a DNA expression construct for intradermal injection to elicit a type 1 cellular mediated immune response where the DNA expression construct is a covalently closed linear DNA molecule comprising a linear double stranded region comprising a coding sequence under control of a promoter, where the single strands forming the double strand are linked a short single stranded loops of DNA, and where the construct is covalently linked to an oligopeptide. The applicant further claims a vaccine employing said construct.

Wittig et al. teaches dumbbell shaped DNA expression constructs comprising covalently closed linear DNA that contains only a coding sequence operably linked to a promoter and polyA termination sequence where the linear ends are linked by short single stranded loops of DNA, and wherein the construct is further covalently linked to a peptide which directs transport of the construct across a cell's endosome or into the nucleus (Wittig et al., claims 1-11, and columns 5-8)). Wittig et al. also teaches that the coding sequence can encode various cytokines, including Th1 cytokines such as IL-12, and methods of administering the constructs including intradermal administration (Wittig et al., columns 1, 8, and 13). Wittig et al. also teaches a vaccine comprising this construct (Wittig et al., column 8).

Regarding the intended use as recited in the instant claims for intradermal injection to elicit a type 1 cellular mediated immune response, the applicant is reminded that the use of a product for a particular purpose is not afforded patentable weight in a product claim where the body of the claim does not depend on the preamble for completeness but, instead, the structural limitations are able to stand alone. The MPEP states that,".. in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art." *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto* , 136 USPQ 458, 459 (CCPA 1963)(MPEP 2111.02). Further, the intended use of the compound does not constitute a step in the method as claimed. As noted previously in this office action, the "Use" claims do not comprise any actual method steps. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure or composition, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. *In re Hirao* , 535 F.2d 67, 190 USPQ 15 (CCPA 1976); *Kropa v. Robie* , 88 USPQ 478, 481 (CCPA 1951). As such, by teaching the exact structural elements of the claims as written, Wittig et al. anticipates the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6, 10-14, and 16 rejected under 35 U.S.C. 103(a) as being unpatentable over Schirmbeck et al. (June 2001) J. Mol. Med., Vol. 79, 343-350 in view of U.S. Patent No. 6,451,593 (2002), hereafter referred to as Wittig et al., and Liu et al. (2001) Biomacromolecules, Vol. 2, 362-368. The applicant claims a "use" of a DNA expression construct for intradermal injection to elicit a type 1 cellular mediated immune response where the DNA expression construct is a covalently closed linear DNA molecule comprising a linear double stranded region comprising a coding sequence under control of a promoter, where the single strands forming the double strand are linked a short single stranded loops of DNA, and where the construct is covalently linked to an oligopeptide. The applicant further claims said construct wherein the construct encodes HBsAg, and wherein the oligopeptide comprises YGRKKRRQRRR.

Regarding the intended use as recited in the instant claims for intradermal injection to elicit a type 1 cellular mediated immune response, the applicant is reminded that the use of a

product for a particular purpose is not afforded patentable weight in a product claim where the body of the claim does not depend on the preamble for completeness but, instead, the structural limitations are able to stand alone. The MPEP states that,".. in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art." *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto* , 136 USPQ 458, 459 (CCPA 1963)(MPEP 2111.02). Further, the intended use of the compound does not constitute a step in the method as claimed. As noted previously in this office action, the "Use" claims do not comprise any actual method steps. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure or composition, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. *In re Hirao* , 535 F.2d 67, 190 USPQ 15 (CCPA 1976); *Kropa v. Robie* , 88 USPQ 478, 481 (CCPA 1951).

Schirmbeck et al. teaches a minimal expression construct (MIDGE) comprising covalently closed linear DNA that contains only an HBsAG coding sequence operably linked to CMV promoter and polyA termination sequence where the linear ends are linked by short single stranded loops of DNA, and wherein the construct is further covalently linked to the NLS oligopeptide PKKKRKVEDPYC (Schirmbeck et al., page 345, Figure 1 B.3). Schirmbeck et al. also teaches a vaccine comprising this construct (Schirmbeck et al., page 343).

Schirmbeck et al. differs from the instant invention by not teaching that the peptide which directs transport is the oligopeptide YGRKKRRQRRR. Wittig et al. supplements Schirmbeck et al. by teaching dumbbell shaped DNA expression constructs comprising covalently closed linear

DNA that contains only a coding sequence operably linked to a promoter and polyA termination sequence where the linear ends are linked by short single stranded loops of DNA, and wherein the construct is further covalently linked to a peptide which directs transport of the construct across a cell's endosome or into the nucleus (Wittig et al., claims 1-11, and columns 5-8)). Wittig et al. further teaches a vaccine comprising this construct for treating infectious diseases and the intradermal administration of the construct (Wittig et al., columns 1 and 8). Wittig et al. thus provides motivation for using any oligopeptide that can direct transport of the construct across a cell's endosome or into the nucleus.

Liu et al. supplements both Wittig et al. and Schirmbeck et al. by teaching that the oligomeric peptide sequence YGRKKRRQRRR from the protein transduction domain of HIV TAT protein mediates the transduction of molecules covalently attached to the peptide into cells (Liu et al., page 363, column 1). Therefore, based on the motivation provided by Wittig et al. that various oligopeptides can be linked to minimal expression constructs to facilitate transport of the construct into a cell, it would have been *prima facie* obvious to the skilled artisan at the time of filing to attach the oligopeptide YGRKKRRQRRR to a MIDGE construct encoding HBsAG instead of the oligopeptide PKKKRKVEDPYC as taught by Schirmbeck. Further, based on the specific guidance provided by Schirmbeck et al. for attaching an oligopeptide to a MIDGE construct and the specific guidance for synthesizing the oligopeptide YGRKKRRQRRR provided by Liu et al., the skilled artisan would have had a reasonable expectation of success in making a MIDGE DNA expression construct encoding HBsAg covalently attached to YGRKKRRQRRR.

No claims are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197. Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER